a centralized point for each manufacturer or distributor within the United States.

[58 FR 43447, Aug. 16, 1993, as amended at 65 FR 43690, July 14, 2000]

### § 821.55 Confidentiality.

(a) Records and other information submitted to FDA under this part shall be protected from public disclosure to the extent permitted under part 20 of this chapter, and in accordance with § 20.63 of this chapter, information contained in such records that would identify patient or research subjects shall not be available for public disclosure except as provided in those parts.

(b) Patient names or other identifiers may be disclosed to a manufacturer or other person subject to this part or to a physician when the health or safety of the patient requires that such persons have access to the information. Such notification will be pursuant to agreement that the record or information will not be further disclosed except as the health aspects of the patient requires. Such notification does not constitute public disclosure and will not trigger the availability of the same information to the public generally.

EFFECTIVE DATE NOTE: At 67 FR 5952, Feb. 8, 2002, § 821.55 was amended by redesignating paragraphs (a) and (b) as paragraphs (b) and (c), respectively, and by adding a new paragraph (a), effective May 9, 2002. For the convenience of the user, the added text is set forth as follows:

### § 821.55 Confidentiality.

(a) Any patient receiving a device subject to tracking requirements under this part may refuse to release, or refuse permission to release, the patient's name, address, telephone number, and social security number, or other identifying information for the purpose of tracking.

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### § 821.60 Retention of records.

Persons required to maintain records under this part shall maintain such records for the useful life of each tracked device they manufacture or distribute. The useful life of a device is the time a device is in use or in distribution for use. For example, a record may be retired if the person maintaining the record becomes aware of the fact that the device is no longer in use, has been explanted, returned to the manufacturer, or the patient has died.

# PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

## Subpart A—General



## Subpart B—Classification



## Subpart C—Reclassification



AUTHORITY: 21 U.S.C. 360c, 360d, 360e, 360i, 360j, 371, 374.

SOURCE: 43 FR 32993, July 28, 1978, unless otherwise noted.

## Subpart A—General

### § 860.1 Scope.

(a) This part implements sections 513, 514(b), 515(b), and 520(l) of the act with respect to the classification and reclassification of devices intended for human use.

(b) This part prescribes the criteria and procedures to be used by classification panels in making their recommendations and by the Commissioner in making the Commissioner's